CORMAY

Digitally signed by Iurchevici Valeriu
Date: 2021.12.06 15:24:05 EET
Reason: MoldSign Signature
Location: Moldova

PZ CORMAY S.A.
Wiosenna 22 street
05-092 Łomianki
tel.: +48 22 751 79 10
fax: +48 22 751 79 11
www.cormay.pl

Warsaw, 3rd December 2021

Letter of Authorization

WHEREAS,

We, PZ Cormay S.A., represented by its President Mr. Janusz Płocica and Vice-President Mr. Wojciech Suchowski, incorporated under entry No. KRS 0000270105 with The National Court Register in Poland having its headquarter at 22, Wiosenna, 05-092 Lomianki, Poland, hereby authorize:

"Echipamed-Plus" SRL
Moldova, MD-2001, Chisinau,
str. Valea Trandafirilor 24B, of. 2-7

As our exclusive representative in Moldova for Cormay biochemistry reagents dedicated for following automated biochemistry analyzers:

- BS series

"Echipamed-Plus" SRL will be responsible for purchasing reagents exclusive from Cormay, selling, clearance, promotion and service of the Cormay biochemistry reagents dedicated for BS series.

The same reagents dedicated for Cormay Accent series analyzers are not a topic of this agreement.

This letter will remain valid until 31.12.2022.

On behalf of PZ Cormay S.A.

Janusz Płocica
President
PZ Cormay S.A.

Wojciech Suchowski
Vice-Presiedent
PZ Cormay S.A.

Lloyd's Register

Current issue date:	17 August 2021	Original approval(s):
Expiry date:	16 August 2024	ISO 13485 - 17 August 2009
Certificate identity number:	10370649	ISO 9001 - 16 January 1998

Certificate of Approval

This is to certify that the Management System of:

PZ CORMAY Spółka Akcyjna

ul. Wiosenna 22, 05-092 Łomianki, Poland

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016, ISO 9001:2015

Approval number(s): ISO 13485 – 0053001, ISO 9001 – 0053000

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design, production and distribution of reagents of in vitro diagnostics for medical, industrial and scientific laboratories and design, production, sales and maintenance of in vitro diagnostic medical-devices.

Paul Graaf

Chief Operating Officer, Management Systems, MSIS

Issued by: Lloyd's Register (Polska) sp. z o.o.

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS 0001

PZ CORMAY S.A.
05-092 Lomianki, 22 Wiosenna Str.
phone: +48 22 751 7910 ; fax: +48 22 751 7911
www.cormay.pl; office@cormay.pl

ISO 9001 Quality Management System

ISO 13485 Quality Management System

EC DECLARATION OF CONFORMITY

In accordance with Directive 98/79/EC

We, **PZ CORMAY S.A.,** ul. Wiosenna 22, 05-092 Łomianki, Poland
declare that the following devices:

Devices name: see ATTACHMENT A

Devices number: see ATTACHMENT A

(classified as other IVDD - all devices with exception of devices listed in List A and List B and self-testing devices)
comply with essential requirements of the ANNEX I - Directive 98/79/EC
and conformity assessment made accordingly to the ANNEX III - Directive 98/79/EC.

The devices named above have been designed and manufactured to the following specifications:

EN ISO 14971:2000	Medical Devices – Application of risk management to medical devices.
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents.
EN 375:2001	Information supplied by the manufacturer with in vitro diagnostic reagents for professional use.
EN 980:2006	Graphical symbols for use in the labeling of medical devices.
EN 13640: 2002	Stability testing of in vitro diagnostic reagents.
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices.

PZ CORMAY S.A Quality Management System complies with requirements of ISO 9001:2008 and ISO 13485:2003 standard and has been approved by Lloyd's Register Quality Assuarance Limited in the range concerning design, manufacturing and distribution of in vitro diagnostic medical devices for medical, industrial and research laboratories. Sale and service of medical equipment.

Signed by: .....

Name: Tomasz Tuora

Position: President PZ CORMAY S.A.

Place: Łomianki

Date: 16 September, 2010

Attachment A to the EC DECLARATION OF CONFORMITY

Device number	Device name
5-174	CORMAY MULTICALIBRATOR LEVEL 1
5-176	CORMAY MULTICALIBRATOR LEVEL 1
5-175	CORMAY MULTICALIBRATOR LEVEL 2
5-177	CORMAY MULTICALIBRATOR LEVEL 2
5-170	CORMAY MULTICAL
5-178	CORMAY HDL/LDL CALIBRATOR
4-287	CORMAY IMMUNO-MULTICAL
4-289	CORMAY APOLIPOPROTEIN CALIBRATORS
4-292	CORMAY FIBRINOGEN CALIBRATOR
4-295	CORMAY CRP NORMAL CALIBRATOR
4-276	CORMAY CRP ULTRA CALIBRATORS
4-279	CORMAY MYOGLOBIN CALIBRATORS
4-281	CORMAY Lp(a) CALIBRATORS
4-491	CORMAY FERRITIN CALIBRATORS
4-280	CORMAY IgE CALIBRATORS
4-282	CORMAY AFP CALIBRATORS
4-283	CORMAY BETA 2-MGLOB CALIBRATORS (S)
4-284	CORMAY BETA 2-MGLOB CALIBRATORS (U)
4-286	CORMAY ALPHA 1-MGLOB CALIBRATORS (S)
4-285	CORMAY ALPHA 1-MGLOB CALIBRATORS (U)
4-277	CORMAY RF CALIBRATORS
4-278	CORMAY ASO CALIBRATOR
4-318	CORMAY HbA1c CALIBRATORS
4-308	CORMAY HbA1c DIRECT CALIBRATORS
5-182	CORMAY CK-MB CALIBRATOR
4-259	CORMAY D-DIMER CALIBRATOR
5-181	CORMAY URINE PROTEINS CALIBRATORS
5-185	CORMAY CYSTATIN C CALIBRATORS
5-105	CORMAY ETHANOL CALIBRATORS
5-106	CORMAY ETHANOL CALIBRATOR 100
5-112	CORMAY CARBAMAZEPINE CALIBRATORS
5-114	CORMAY DIGITOXIN CALIBRATORS
5-113	CORMAY DIGOXIN CALIBRATORS
5-110	CORMAY GENTAMICIN CALIBRATORS
5-111	CORMAY PHENOBARBITAL CALIBRATORS
5-109	CORMAY THEOPHYLLINE CALIBRATORS
4-380	CORMAY BILIRUBIN CALIBRATOR

Signed by:.....

Name: Tomasz Tuora

Position: President PZ CORMAY S.A.

Place: Łomianki

Date: 16 September, 2010

REPUBLICA MOLDOVA mun. CHIȘINĂU, SOCIETATEA CU RASPUNDERE LIMITATA "TECHNIPAMED-PLUS" IDNO 1003600077677

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Signed by:.....

Name: Tomasz Tuora

Position: President PZ CORMAY S.A.

Place: Łomianki

Date: 08 January, 2010

Attachment A to the EC DECLARATION OF CONFORMITY

Device number	Device name
5-172	CORMAY SERUM HN
5-173	CORMAY SERUM HP
4-288	CORMAY IMMUNO-CONTROL I
4-290	CORMAY IMMUNO-CONTROL II
4-291	CORMAY IMMUNO-CONTROL III
4-492	CORMAY Lp (a) CONTROL N
4-493	CORMAY Lp (a) CONTROL P
5-179	CORMAY LIPID CONTROL 1
5-180	CORMAY LIPID CONTROL 2
4-319	CORMAY HbA1c CONTROLS
4-328	CORMAY HbA1c DIRECT CONTROLS
4-293	CORMAY APOLIPOPROTEIN CONTROL
4-459	CORMAY D-DIMER CONTROLS
5-183	CORMAY CK-MB CONTROL N
5-184	CORMAY CK-MB CONTROL P
5-161	CORMAY URINE CONTROL LEVEL 1
5-162	CORMAY URINE CONTROL LEVEL 2
4-460	CORMAY CYSTATIN C CONTROLS
5-163	CORMAY AMMONIA/ETHANOL CONTROLS
5-108	CORMAY DIGITOXIN CONTROLS
5-107	CORMAY TDM CONTROLS

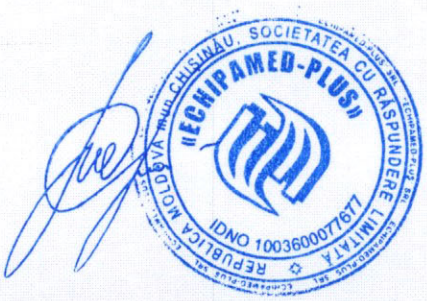
Signed by:.....

Name: Tomasz Tuora

Position: President PZ CORMAY S.A.

Place: Łomianki

Date: 08 January, 2010



CIS-AL-LI373-66602101

mindray

"Echipamed-Plus" SRL
str. Valea Trandafirilor, 24B, of. 2-7
MD-2001, Chisinau, Moldova
+373 22 234-349

January 27th, 2021

LETTER OF AUTHORIZATION

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, **("Mindray")** manufacturer of **BS-120, BS-200, BS-240, CL-900i, CL-1000i, CL-1200i, corresponding reagents and consumables ("Products")**, hereby certify that we authorize **"Echipamed-Plus" SRL,** with business office at **str. Valea Trandafirilor, 24B, of. 2-7, MD-2001, Chisinau, Republic of Moldova ("You")** as the exclusive distributor and local representative for sales and service of the Products in **Republic of Moldova ("Territory").**

As the manufacturer, Mindray guarantees the Products against defects in materials and workmanship, and provide services based on the standard terms and conditions of Mindray's warranty policy.

This authorization of distribution rights is valid from the date of issuance to **December 31, 2021.** Mindray reserves the right to terminate the authorization upon fifteen (15) days written notice without any compensation to You.

Neither this Letter of Authorization nor any further extension, will impose any obligation or grant any rights regarding further distribution of the Products, nor allow any party to seek compensation for goodwill developed during the term of Letter of Authorization or any further extension.

Best regards,

Duan Liang
Sales Manager of Sales and Marketing Division, CIS
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.
Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R. China
Tel: +86 755 81888998
Fax: +86 755 26582680
Website: www.mindray.com

SOCIETATEA CU RASPUNDERE LIMITATA "ECHIPAMED-PLUS" IDNO 1003600077677 REPUBLICA MOLDOVA MUN. CHISINAU

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

SCC Accredited CB-MS
OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Certificate Holder:

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD ISO 9001

Scope of Certificate: **See Page 2 for Overall Scope Statement.**

Standard(s): **ISO 9001:2015**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: **SH2005501**

Effective Date: **2020-08-12**

Expiry Date: **2023-06-30**

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

TÜV®

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Chemistry Analyzer**
Model:	**BS-240**
Consumables:	Reaction cuvette Mindray reagent bottles CD-80 DETERGENT
Optional Module:	ISE unit bar code reader(optional)
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

Conformity Assessment Route: IVDD Annex III (not includes Section 6)

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Start of CE-Marking: 2016-03-29

Place, Date of Issue: Shenzhen, 2016.3.29

Signature: .....

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company: Manager of Technical Regulation

MOLDOVA mun.CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TEHNIPAMED-PLUS" REPUBLICA